November 1, 1999

Attachment 6

# Continuing Experience Policy

For Additional Information, Contact:
Joanne K. Choy, Coordinator, MQSA
Inspector Quality Assurance
Email address: JKC@FDA.CDRH.GOV
Phone: 301-827-2963
Fax: 301-594-3306

November 1, 1999

# Continuing Experience Policy for Mammography Quality Standards Act (MQSA) Certified Inspectors

## Purpose and Goal

To ensure proficiency, accuracy and reliability of MQSA-certified inspectors in performing MQSA inspections, the Food and Drug Administration (FDA) has established a continuing experience policy requiring inspectors to perform a minimum number of inspections to maintain their status as MQSA inspectors.

## Background

In 1996, FDA Headquarters and Regional Radiological Health Representatives (RRHRs) extensively discussed instituting a minimum number of inspections, depending on an inspector's status (general, backup or supervisory) in order to define the minimum number of inspections an inspector must complete to reasonably assure inspector proficiency. Likewise, FDA surveyed State and FDA MQSA inspectors to elicit their input on requirements for a minimum number of inspections per year. The findings resulted in recommendations to require from zero to over 50 inspections per year. Some States felt there should be a single minimum number while others preferred different minimums for different categories of inspectors. FDA also considered the complexity of the MQSA inspection procedures and the necessity for inspectors to stay current with evolving inspection policies in developing a continuing experience policy. From this analysis, FDA established a minimum requirement of twelve (12) inspections per year for all MQSA inspectors.

In Spring 1997, FDA contracted with a private consulting firm to conduct "A Customer Service Survey Among Mammography Facilities - An Assessment of Facility Experiences and Opinions." In this survey, FDA randomly polled 1,000 mammography facilities concerning their facility's experiences with MQSA inspections. The survey examined four components of the MQSA inspection-- pre-inspection preparation (e.g., educational materials), the actual inspection process, inspector performance, and inspection results. Of the 674 surveys returned, data revealed, among other things, that facility satisfaction with an inspection significantly depended on the number of inspections an inspector had performed. Facilities expressed greater satisfaction with the inspection process with inspectors who had performed more than 10 previous inspections, with no correlation of practical significance between satisfaction and compliance findings.

Therefore, FDA believes that a specified minimum number of inspections is necessary for inspectors to maintain their expertise. (NOTE: Reference the "MQSA Inspector Continuing Education Policy" and "Inspector Audit Policy" for additional requirements established by FDA to support inspectors excellence in their performance of thorough and quality inspections).

November 1, 1999

Policy

Minimum Inspections Required to Maintain Active Status

Following the second anniversary date of certification and annually thereafter, an MQSA-certified Inspector shall have performed an average of twenty-four (24) MQSA inspections during the 24 months immediately preceding the date of the inspector's annual MQSA audit, the last day of the calendar quarter preceding the audit or any date in between the two. The inspector will choose one of these dates to determine the 24-month period that the MQSA FDA Auditor shall use to confirm that his/her continuing experience requirements were met. The inspector may change the 24-month period assessed each year.

Acceptable Inspection Types

The following inspection types count toward meeting the continuing experience requirement:

- Annual certified facility inspections (includes federal facilities, comprising U.S. federal, VHA and U.S. foreign military facilities)
- Joint (J) Audit inspections (count for both the inspector and FDA auditor) - FDA Auditors and Inspectors are reminded to indicate a "J" (for Joint inspection) in the MPRIS system and identify the auditor's inspector number in the "Facility Inspections-Inspection" screen.
- Mentored (M) inspections (count for both the mentored State/FDA inspector and accompanying FDA/State inspector). To obtain credit for the mentored inspections, inspectors should select "M" for "Mentored" in the annual inspection type screen and select the appropriate accompanying inspector.

***NOTE: Follow-up or headquarters initiated inspections, which are normally conducted by FDA inspectors and typically examine only limited items, will not count.***

Acceptable Documentation of Continuing Experience

At the inspector's annual audit*, the auditor shall verify the number of inspections performed as outlined above (Reference Minimum Inspections Required to Maintain Active Status) and document the number of inspections performed by the inspector in his/her audit report. Verification may be ascertained by accessing the Facility Noncompliance Tracking Management System (FaNTMS). Although tracked by the MQSA FDA Auditor, it is the individual inspector's responsibility to ensure compliance

*To avoid additional facility disruption, auditors will physically perform the inspectors records assessment just prior to or following the audit.

with the continuing experience requirement. Inspectors should be prepared to provide supporting documentation at the annual audit confirming inspections performed to include inspection date, facility ID, facility name and inspection type. This documentation is especially critical for Mentored inspections (where the inspector is the "mentoring" inspector), for Joint Audit inspections (in the case of Auditors) and for Veterans Health Administration inspections as these inspections will not be included in the inspector's official count accessible by the Auditor.

Steps for Reestablishing Qualifications for Certification

Inspectors who do not to meet the continuing experience requirement will be considered an inactive inspector and cannot perform independent inspections. In order to be reactivated, an inspector shall:

- perform the balance needed to meet the continuing experience requirements or three* inspections under the direct mentoring of an MQSA-certified inspector , whichever is less, within the six months immediately prior to resuming independent inspections. The mentoring inspector shall be designated after consultation with the appropriate FDA Regional Radiological Health Representative(s). The inspector being audited should provide documentation of his/her mentoring and associated results to the auditor at the time of the next audit (Reference Enclosure 1)+.

After meeting the requirements, the inspector is still responsible for maintaining his/her 24 inspections in the 24-month period, preceding an audit. Further, the date on which the inspector was initially certified as an MQSA inspector does not change due to taking time off or not meeting the continuing experience requirement.

*The requalification requirement mirrors the facility personnel requalification requirements for radiologic technologists which states that an R.T. must perform 25 examinations under direct supervision (25 exams are 12% of the 200 examinations required in initial training; three inspections are 12% of 24 inspections).

+If an inspector is not meeting his/her continuing experience requirements because there are not enough facility inspections available for him/her to perform, inspectors may not automatically implement requalification procedures. Instead, the State or FDA District Office must contact their Regional Radiological Health Representative within their area for discussion of this issue and resolution by FDA's Division of Mammography Quality and Radiation Programs.

Note: The date on which the inspector was initially certified as an MQSA inspector does not change due to taking time off or not meeting the continuing experience requirements.

November 1, 1999

Draft:Jchoy:October 1, 1997
ReDraft:Jchoy:10/1/97
ReDraft:Jchoy:10/2/97
ReDraft:Jchoy:10/3/97
Redraft:Jchoy:Sbelella:10/20/97
Redraft:Jchoy:12/11/97
Redraft:Jchoy:Pplatt:12/12/97
Revised:Kfranke:12/12/97
Revised:Wmourad:12/15/97
Revised:Cchrvala:12/15/97
Revised:Fhoun:12/17/97
Revised:Jchoy:12/22/97
Revised:1/15/98
Revised:Cchrvala:Jchoy:1/16/98
Revised:Cchrvala:Jchoy:1/22/98
Revised:3/26/98:Jchoy
Revised:4/14/98:Jchoy
Revised:6/4/98
Revised:11/6/98:Jchoy
Consult with DZS:12/1/98
Revised:12/1/98:Jchoy
Revised:Kfranke:Sbelella:Jchoy:12/15/98
Revised:Jchoy:1/26/99
Revised:Jchoy:2/2/99
To Kfranke:Wmourad:Rpack:Sbelella:Drobinson:Pplatt:2/2/99
Revised:3/2/99
ToJLM:3/2/99 via KAF
JLM:3/24/99
To FDA Auditors/RRHRs/H-11 Mammography Committee 5/99
CommentsReceived:5/99 and 6/99
Revisions:Jchoy:FDAAuditors:RRHRs:H-11Mammography Committee:Kfranke:7/99
Revisions:Jchoy:8/24/99
Revisions:J Choy:J McCrohan:K Franke:9/21/99
Revisions:Jchoy:9/28/99